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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-----------------------------------|
| 10/634,335 | 08/04/2003 | Jean-Marc DuFour | DRXI-0144 | 6769 |
| 23377 | 7590 | 11/30/2006 | | EXAMINER JONES, DAMERON LEVEST |
| WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891 | | | ART UNIT 1618 | PAPER NUMBER |

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 10/634,335 | DUFOUR, JEAN-MARC | |
| Examiner | Art Unit | | |
| D. L. Jones | 1618 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 August 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,4,6-9,11,12,14-16,18,22-25,27,31 and 37-45 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1,3,4,7-9,11,12,15,16,18,22-25 and 37-39 is/are allowed.

6) Claim(s) 6, 14, 27, 31, and 40-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ . 5) Notice of Informal Patent Application
6) Other: ____ .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/31/06 wherein claims 1, 9, 16, 27, and 31 are amended; claims 2, 5, 10, 13, 17, 19-21, 26, 28-30, and 32-36 are canceled; and claims 40-45 are added.

Note: Claims 1, 3, 4, 6-9, 11, 12, 14-16, 18, 22-25, 27, 31, and 37-45 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/06 has been entered.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and/or amendment filed 8/31/06 to the rejection of claims made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive. Therefore, the said rejection is hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejections (Written Descriptions)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 27, 31, and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of administering a compound complexed with a radionuclide, but do not identify for what condition the complex is being administered. As a result, the invention has not been described with such clarity that the reader is assured that the inventor actually has possession and knowledge of the method useful with the complex that is worthy of patent protection. Review of the specification, for example, (see PG Pub 2004/0086460, page 8, paragraph [0074] and page 9, paragraph [0083]) indicates that the compound of the instant invention are used as diagnostic imaging agents for visualizing metastases and tumors wherein the tumors are selected from the group consisting of pituitary, gastroenteropancreatic, central nervous system, breast, prostate, ovarian, colon, small cell lung, paragangliomas, neuroblastomas, pheochromocytomas, medullary thyroid, carcinomas, myelomas, and lymphomas. However, the claims as written are not consistent with the disclosure of the specification.

112 Second Paragraph Rejections

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6, 14, 27, 31, and 40-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 14: Did Applicant intend to insert 'tert-butoxycarbonyl' in claims 1 and 9? If so, then the appropriate changes should be made and claims 6 and 9 should be canceled since the limitations of the claims will be incorporated into claims 1 and 9.

Claims 27, 31, and 40-45: The claims as written are ambiguous because it is unclear for what purpose the compound is being administered to a subject. For example in claim 40-42, the compound is being administered to a subject in need thereof; however, it is unclear if whether the subject is in need of cancer treatment, detecting cholesterol levels, understanding renal function, imaging coronary tissue, determining whether the subject is diabetic, controlling coughing associated with asthma, etc. In other words, a method of administering a compound does not set forth the reasoning as to why the compound is being administered. Hence, one cannot ascertain what are the metes and bounds of the invention. Note: Since claims 27 and 31 depend on claims 40 and 43 that are unclear, those claims (27 and 31) are also ambiguous.

Likewise, claims 43-45 are ambiguous because it is unclear what condition actually deems necessary the administering of the therapeutic amount of the compound

complexed with a radionuclide. It appears as if Applicant is treating tumors, but due to the manner in which the claim is written, it is not clear. Did Applicant intend to write, 'A method of treating a disease comprising administering to an animal in need thereof an effective amount of a compound according to claim 1 complexed with a radionuclide wherein said disease is selected from the group consisting of pituitary tumors, gastroenteropancreatic tumors...and lymphomas'. Furthermore, claims 43-45 contain improper Markush terminology. As a result, it is not clear what the actually metes and bounds of the claims are since the condition which deem necessary the administering of the compound and radionuclide is unclear and the open Markush terminology that is being used in the claims. Applicant is respectfully requested to review MPEP 803.02 for acceptable Markush terminology.

ALLOWABLE CLAIMS

8. Claims 1, 3, 4, 7-9, 11, 12, 15, 16, 18, 22-25, and 37-39 are allowable over the prior art of record.

COMMENTS/NOTES

9. The following changes are respectfully suggested in order to clarify the instant invention: (1) claim 37: the claim should be amended to only contain the information directed to the carboxylic acid and isothiocyanate groups since claim 1 contains the other information present in the claim; (2) claim 38: the claim should be amended to only contain the information directed to the carboxylic acid and isothiocyanate because the other information is present in claim 9; and (3) claim 39: the claim should be

amended to only contain the information directed to the carboxylic acid and isothiocyanate because the other information is present in claim 16.

10. It is once again noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the 112 rejections above. The claims are allowable over the prior art of record for reasons of record in the office action mailed 3/8/05.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

November 27, 2006